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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/599,500 | 09/29/2006 | Jong Soo Woo | Q97453 | 9881 |

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| EXAMINER | |
|---|---|
| HUANG, GIGI GEORGIANA | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1612 | |

| MAIL DATE | DELIVERY MODE |
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| 08/19/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/599,500 | WOO ET AL. | |
| | Examiner | Art Unit | |
| | GIGI HUANG | 1612 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/29/2006* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### Request for Continued Examination

### *Status of Application*

1. The response filed June 13, 2008 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claim 1 has been amended.

2. Claims 1-4 are pending in the case.

3. Claims 1-4 are present for examination.

4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

5. All grounds not addressed in the action are withdrawn or moot.

6. New grounds of rejection are set forth in the current office action.

### *New Grounds of Rejection*

7. Due to the amendment of the claims and the request for continued examination, the new grounds of rejection are applied:

### *Claim Rejections - 35 USC § 112*

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "pharmaceutically acceptable additive" is indefinite as it unclear what is encompassed by the term. Although the specification provides examples such as diluents and lubricants, there is no definition stating that the term "pharmaceutically acceptable additive" is to excipients and is unclear to what compounds, drugs, polymers, and materials that are of pharmaceutical grade that are encompassed by the term. The additive can be anything and thereby it is unclear what is envisioned for the invention. It does not allow one of skill in the art to know the metes and bounds of the invention. For purposes of prosecution, any material applies.

10. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "weight ratio" is indefinite as it unclear what is encompassed by the term. It is unclear if the ratio is the weight of the materials (e.g. grams) or the weight percentage of the components in the composition. It does not allow one of skill in the art to know the metes and bounds of the invention.

For purposes of prosecution, any weight ratio is used.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berner et al. (U.S. Pat. Publication 2003/0104062).

Berner et al. teaches a pharmaceutical control release dosage form for drugs preferably high solubility drugs including and exemplifying metformin hydrochloride. The composition comprises water-swellable polymers in the core and shell to achieve appropriate control release. The suitable polymers include polyalkylene oxides, xanthan gum, and polysaccharide gums (i.e. natural gums, e.g. xanthan). The preferred polyalkylene oxides are polypropylene oxide and polyethylene oxide where the more preferred molecular weight for the polyethylene oxide is about 4,000,000 to about 8,000,000, the particular polyethylene oxides used are POLYOX®NF (5 million), POLYOX®WSR301 (4million), POLYOX®NWSR303 (7 million), POLYOX®WSR N-60K (2 million). The preferred range of the viscosity-average molecular weight ratio of core: shell is about 0.2:1 to about 1:1. The weight ratio of the drug to polymer in the core may vary as Berner teaches that optimal ratios will depend on the therapeutic dose, solubility of the drug, desired release rate, polymer, molecular weight, and the types and amount of excipients used.

Example 1 teaches a compressed core and shell tables of metformin hydrochloride. The core has metformin hydrochloride at 9.374 parts by weight, POLYOX® 301 at 5.478 parts, magnesium stearate at 0.151 parts by weight. A 600 mg portion formed the core (results in metformin 375mg, POLYOX®301 219 mg, magnesium stearate 6mg-parts/total parts multiplied by 600mg) and a shell weight of 200mg of POLYOX®303. The ratio of drug to carrier is 0.895, the ratio of polyethylene

oxide in the core to the shell is 1.095 (Abstract, Paragraph 51, 56-71, 74-80, 83, 89-90, 109-110).

Berner et al. does not expressly teach an example with a natural gum such as xanthan gum in a metformin composition with polyethylene oxide.

Berner et al. does teach that polyethylene oxide and polysaccharide gums, particularly xanthan gum, are analogous water-swellable polymers.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute xanthan gum or other natural polysaccharide gums for polyethylene oxide in the core or the shell in Example 1, as suggested by Berner et al., and produce the instant invention. It would have been obvious to substitute one material for another depending on the desired appropriate control release, availability, and properties for the final product.

One of ordinary skill in the art would have been motivated to do this because it is desirable for manufacturers to have analogous choices to substitute the water-swellable polymers in the core and shell to achieve appropriate control release when motivated by pricing, availability, or desired properties of the final product.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the

time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

***Response to Arguments***

13. Applicant's arguments filed 6/3/2008 are moot in light of the amendments and the new grounds of rejection. It is noted however that the comparative examples, declaration, and argument are not commensurate in scope with the claims as the claims do not include the components present in the comparative or declaration or the composition design. Additionally the profiles are to the future intended use which does not have patentable weight in composition claims.

***Conclusion***

14. Claims 1-4 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612